

K012640

**Medical Instruments Technology, Inc's.  
Reprocessed Electrosurgical Wand Premarket Notification**

**Medical Instruments Technology Inc.**

**FEB 28 2002**

Quality Reprocessing and Surgical Cost Containment Systems

**Section 12: 510k Summary**

**Name of Submitter**

Medical Instruments Technology, Inc.  
385 North 3050 East  
Saint George, UT 84790  
Tel: (435) 674-4010  
Fax: (435) 674-9819

**Contact persons**

Tom Haueter, RA/QA Manager  
Crystal Batcabe, Assistant RA/QA Manager

Summary Prepared August 10, 2001

**Device Name and Classification**

Common Name: Electrosurgical Cutting and Coagulation Accessories,  
Electrosurgical Wands  
Classification: Class II per 21 CFR 878.4400

**Predicate Device**

MIT's reprocessed electrosurgical cutting and coagulation accessories are substantially equivalent to: Mitek (K974022) or Arthrocare Wands (K962321)

**Description of Device**

The cutting and coagulation system consists of a system controller that is connected to a power source. Two cables extend from the system controller, one to a foot-pedal to allow the operator to control the device; the other cable leads to the wand portion, which functions in the surgical site. The wand is the accessory for which MIT has developed the reprocessing technology.

**Intended Use**

The intended use of the cutting and coagulation accessory is to ablate tissue and/or cauterize. The devices are indicated for use in joints such as, ankles, knees, hips, wrist, elbow, and shoulders. They are supplied sterile.

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**Technological Characteristics**

MIT's reprocessed electrosurgical devices have the same technological characteristics as the predicate devices. MIT does not change any of the design characteristics or materials during reprocessing. The only material change, that MIT does make, is that of the sheathing. The sheathing is replaced, because the original sheathing would be damaged in the reprocessing procedures. The replacement sheathing is substantially equivalent to the original sheathing, and actually acts as a better electrical insulator as shown in the dielectric test.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**FEB 28 2002**

Mr. John P. Batcabe  
Development Manager  
Medical Instruments Technology, Inc.  
385 North 3050 East  
Saint George, Utah 84790

Re: K012640

Trade/Device Name: Reprocessed Electrosurgical Wand  
Regulation Number: 888.1100, 878.4400  
Regulation Name: Arthroscope  
Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: II  
Product Code: HRX, GEI  
Dated: December 4, 2001  
Received: December 11, 2001

Dear Mr. Haueter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

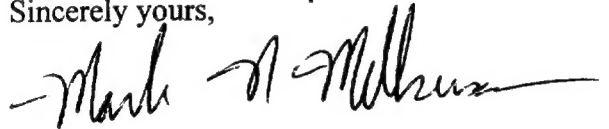
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over a horizontal line.

for Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

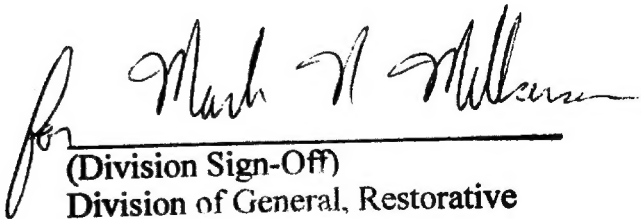
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**Section 3: Indications for Use**

**Intended Use:**

MIT's unique reprocessing of the wands does not change their intended use. The intended use of the cutting and coagulation accessory is to ablate tissue and/or cauterize. The devices are indicated for use in joints such as, ankles, knees, hips, wrist, elbow, and shoulders.

  
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(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K012640